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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,089	10/02/2001	Susheng Wang	EMU3020 US 18055.05310	9533

20786 7590 03/06/2003

KING & SPALDING
191 PEACHTREE STREET, N.E.
ATLANTA, GA 30303-1763

EXAMINER
KIFLE, BRUCK

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 03/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/970,089	Wang et al.
Examiner	**Art Unit**
Bruck Kifle, Ph.D.	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 19, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *5 and 23-36* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *25* is/are allowed.

6) ☒ Claim(s) *5, 23, 24, and 26-36* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *4 and 5*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Restriction

Applicant's election of the compound in claim 25 in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The elected compound was not found in the search. Claim 25 is allowed.

The search was expanded to embrace compounds of claim 5 and their method of use wherein R^1 and R^2, R^2 and R^3, R^3 and R^4, R^4 and R^5 or R^5 and R^6 do not come together to form additional rings.

Improper Markush Rejection

Claims 5, 23, 24 and 26-36 are rejected under a judicially created doctrine as being drawn to an improper Markush group, that is, the claims lack unity of invention. The variables B, D, E R^1, R^2, R^3, R^4, R^5 and R^6 are defined in such a way that it keeps changing the core of the compound that determines the classification. By changing these values, several patentably distinct and independent compounds are claimed. In order to have unity of invention the compounds must have "a community of chemical or physical characteristics" which justify their inclusion in a common group, and that such inclusion is not repugnant to principles of scientific classification" In re JONES (CCPA) 74 USPQ 149 (see footnote 2). The structural formula of claims 5 and 26 do not have a significant structural feature that is shared by all of its alternatives which is inventive. These structures only have a cyclohexane ring as common. This feature is not

inventive. Compounds embraced by the formula in claims 5 and 26 are so diverse in nature that a prior art anticipating a claim with respect to one member under 35 USC 102 would not render obvious the same claim under 35 USC 103. This is evidentiary of patentably distinct and independent inventions.

Limiting the claims to compounds wherein B, D and E are oxygen and where there are no additional ring formations would overcome this rejection.

Claim Rejections - 35 USC § 112

Claims 5, 23, 24 and 26-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) The terms "cycloalkyl", "cycloalkenyl" and "cycloalkynyl" are indefinite because it is not known how many atoms make up the rings and what how many rings are intended (monocyclic, bicyclic, spiro, fused, bridged, etc.).

ii) The terms "heterocyclic", "heteroaryl" and "heteroaromatic" are indefinite because it is not known how many atoms are present, how many and what kind of heteroatoms are involved, what size ring is intended and how many rings are present.

iii) R^1, R^2, R^3, R^4, R^5 and R^6 are defined as "alkcarbonyl", "carbonyl", carboxylic acid", "ester", "carbamate", "amide", "sulfonyl", "sulfanyl", "sulfinyl", "sulfamoyl", "phosphonyl", "phosphinyl", "phosphine", "a residue of a natural or synthetic amino acid" and as "a residue of a natural or synthetic carbohydrate". These are indefinite because they have open valencies

(carbonyl, sulfonyl, etc.), are classes of compounds (amide, acid, ester) and because one cannot say what the metes and bounds of a "residue" is.

iv) Claims 27-32 improperly depend directly or indirectly on claim 25.

v) Claim 5 is drawn to a compound but the last line reads "optionally in a pharmaceutically acceptable carrier." This phrase makes the claim a pharmaceutical composition. Applicants need to either delete the phrase and present a claim drawn to a pharmaceutical composition or rewrite the claim as a pharmaceutical composition claim. See also claim 26.

Claims 5, 23, 24 and 26-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not adequately enabling for the scope of the compounds claimed. The specification not give a reasonable assurance that all, or substantially all of the compounds claimed are useful. The claims are not drawn in terms of a recognized genus but are directed to a more or less artificial selection of compounds.

There is no reason why a claim drawn in this way should not be limited to those compounds which are shown to be both new and useful. An Applicant is not entitled to a claim for a large group of compounds merely on the basis of a showing that a selected few are useful and a general suggestion of a similar utility in the others."

Also, see In re Surrey 151 USPQ 724, regarding sufficiency of a disclosure for a Markush group, and MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the instant pharmaceutical arts. Note in Surrey, in which testing done on a group of homogeneous compounds having the same core was deemed NOT sufficient to support claims to various hetero groups of a much narrower range than is being claimed herein and located at only one position in the formula. The instant scope is enormous, in the millions of compounds, and therefore one compound within its scope is not remotely representative of such a scope. See MPEP 2164.03.

Claims 23, 24 and 26-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The treatment of "autoimmune disorders" generally would be unprecedented feat. For a compound or genus to be effective against "autoimmune disorders" generally is contrary to medical science. The "autoimmune disorders" are a process that can take place in virtually any part of the body. There is a vast range of forms that it can take, causes for the problem, and biochemical pathways that mediate the inflammatory reaction. There are hundreds of such diseases, which have fundamentally different mechanisms and different underlying causes. There are both chronic and acute "autoimmune disorders", most of which lack satisfactory treatment. The intractability of these disorders is clear evidence that the skill level in this art is

low relative to the difficulty of the task. Under such circumstances, it is proper for the PTO to require evidence that such an unprecedented feat has actually been accomplished, In re Ferens, 163 USPQ 609. No such evidence has been presented in this case. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, Genentech vs Novo Nordisk, 42 USPQ2nd 1001, 1006.

Similarly, "inflammation" is not a single disorder which can be treated using a single drug.

Regarding "prophylaxis", this is not remotely enabled because of the difficulty in identifying the host that will come down with an inflammatory disorder or an autoimmune disorder. One cannot say whether the drug prevented these disorders or whether the host did not get this disorder in the first place.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

March 5, 2003

Bruck Kifle
Primary Examiner
Art Unit 1624